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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,104	11/12/2003	Douglas Craig Scott	9118M	5134

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,104	SCOTT ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/26/04;04/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements (IDS) submitted on April 27, 2004, and July 26, 2004 have been considered.

Claim Rejections - 35 USC § 112

The term "safe and effective" in claims 1,18,18,32, and 34 is a relative term which renders the claims indefinite. The term "safe and effective" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "particulate retentive agent" relates to an extremely large number of possible products and has no distinct meaning in the art. Examiner suggest that the limitations in claims 6 should replace the term "particulate retentive agent".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-35 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-17 of copending Application No. 10/706,103. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claims are drawn to an chewable oral care dentifrice composition, having a retention index of 1 to about 4. The only difference between the instant application and the co-pending application is with respect to the retentive agent in claim 7 of the instant application where the retentive agent is hydroxyl-propylmethylcellulose, which is not claimed in the co-pending application. Thus the claims of the instant application are within the scope of the co-pending application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 6-10, 12-16, 30,32 and 34 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Lawlor US 6,706,256 B2.

Lawlor discloses current claims1, 4 and 6 hydrogenated starch (retentive agent) 10% at col. 20 line 66, wherein the composition is non-cariogenic at col. 20 line 43, a chewable solid unit at col. 15 line 46+ where it is referred to as hard and low boiled candy, wherein the composition is less than 65% at col. 15 lines 9-10, wherein the retentive agent is hydroxymethyl cellulose at col. 21 line 51 as in current claims 7 and 8, anticalculus agent at col. 10 line 31(current claim 9), fluoride ions current claims 10 and 12 at col. 11 line 48, the fluoride level is about 200-300 ppm (current claim 13) at col. 11 line 60 +,where the solid unit is a compressed tablet at col. 26 line 62 (current claim 14), wherein the oral carrier is a flavor (current claim 15 at col. 23 line 20+, water soluble buffers as sodium bicarbonate at col. 21 line 62.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor US 6,706,256 B2 in view of Aberg et al., WO 88/10110.

Lawlor teaches current claims1, 4 and 6 hydrogenated starch (retentive agent) 10% at col. 20 line 66, wherein the composition is non-cariogenic at col. 20 line 43, a chewable solid unit at col. 15 line 46+ where it is referred to as hard and low boiled candy, wherein the composition is less than 65% at col. 15 lines 9-10, wherein the retentive agent is hydroxymethyl cellulose at col. 21 line 51 as in current claims 7 and 8, anticalculus agent at col. 10 line 31(current claim 9), fluoride ions current claims 10 and 12 at col. 11 line 48, the fluoride level is about 200-300 ppm (current claim 13) at col. 11 line 60 +,where the solid unit is a compressed tablet at col. 26 line 62 (current claim 14), wherein the oral carrier is a flavor (current claim 15 at col. 23 line 20+, water soluble buffers as sodium bicarbonate at col. 21 line 62, pH 3-10 at co. 22 lines 5+ current claim 28-29.

Aberg et al., teach a non effervescent paste taught as (page 5) as in current claim 17

> Preferably we provide a filling and polishing composition which comprises greater than about 50% by weight of the tablet and a carbon dioxide producing composition comprising less than about 25% by weight of the tablet to prevent excess foaming which would excessively thin the paste. The

Although Aberg did not directly teach non-effervescent from the above, one of ordinary skill in the art would have known to implement the Abergs' teachings for a non-effervescent effect in a tablet because the tablet is chewable and not dissolved in water prior to use. It would have been obvious for deposit of the active agent on the tooth surface when the tablet is chewed upon.

Therefore, one of ordinary skill in the art would have known to combine the teachings of the above cited references to make and used the claimed invention at the time it was made.

One of ordinary skill in the art would have combined the teachings of Lawlor with that of Aberg to make an oral dentrifice tablet that is non-effervescent, chewable, and one that leaves the substantial amount of the composition on the tooth surface. The active agent for the composition of a tooth tablet is well known within the art. One of ordinary skill in the art would know how to prepare a composition of this nature as the techniques are well known to one of ordinary skill in the art.

One of ordinary skill in the art would have been motivated to combine the teachings of the above cited prior art and expect a successful result in doing so,

because the aim of preventive dentistry has been to improve the efficacy of oral hygiene and overall health in mammals.

With regard to the kit Claims:

Lawlor teaches current claims18-26 hydrogenated starch (retentive agent) 10% at col. 20 line 66, wherein the composition is non-cariogenic at col. 20 line 43, a chewable solid unit at col. 15 line 46+ where it is referred to as hard and low boiled candy, wherein the composition is less than 65% at col. 15 lines 9-10, wherein the retentive agent is hydroxymethyl cellulose at col. 21 line 51 as in current claims 7 and 8, anticalculus agent at col. 10 line 31(current claim 9), fluoride ions current claims 10 and 12 at col. 11 line 48, the fluoride level is about 200-300 ppm (current claim 13) at col. 11 line 60 +,where the solid unit is a compressed tablet at col. 26 line 62 (current claim 14), wherein the oral carrier is a flavor (current claim 15 at col. 23 line 20+, water soluble buffers as sodium bicarbonate at col. 21 line 62.

Aberg et al., teach a non effervescent paste (page 5) as in current claim 27

> Preferably we provide a filling and polishing composition which comprises greater than about 50% by weight of the tablet and a carbon dioxide producing composition comprising less than about 25% by weight of the tablet to prevent excess foaming which would excessively thin the paste. The

One of ordinary skill in the art would have combined the above prior art and made a kit that contains the retentive agent-hydrogenated starch, a buffer, in a solid dosage form as a compressed tablet composition at the time the claimed invention was made, in a kit, as this preparation contains the above mention composition/ formulation with packaging information and instructions on how to use/administer.

Therefore, the skilled artisan would have been motivated to combine the above cited reference form a kit and expect a successful result in doing so.

Further, one of skill would have been motivated to combine the above teachings because the drugs used have previously been used for the same function claimed by applicant.

Claims 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawlor, US 6,706,256 B2 in view of Aberg et al., WO 88/10110.

Lawlor teaches current claims 28, 1, 4 and 6 hydrogenated starch (retentive agent) 10% at col. 20 line 66, wherein the composition is non-cariogenic at col. 20 line 43, a chewable solid unit at col. 15 line 46+ where it is referred to as hard and low boiled candy, wherein the composition is less than 65% at col. 15 lines 9-10, wherein the retentive agent is hydroxymethyl cellulose at col. 21 line 51 as in current claims 7 and 8, anticalculus agent at col. 10 line 31(current claim 9), fluoride ions current claims 10 and 12 at col. 11 line 48, the fluoride level is about 200-300 ppm (current claim 13) at col. 11 line 60 +,where the solid unit is a compressed tablet at col. 26 line 62 (current claim 14), wherein the oral carrier is a flavor (current claim 15 at col. 23 line 20+, water soluble buffers as sodium bicarbonate at col. 21 line 62, pH 3-10 at co. 22 lines 5+ current claim 28-29.

Aberg et al., teach a non effervescent paste as (page 5) as in current claim 17

Preferably we provide a filling and polishing composition which comprises greater than about 50% by weight of the tablet and a carbon dioxide producing composition comprising less than about 25% by weight of the tablet to prevent excess foaming which would excessively thin the paste. The

Although Aberg did not directly teach non-effervescent tablet from the above one of ordinary skill in the art would have known to implement the teachings for a non-effervescent effect in a tablet because the tablet is chewable and not dissolved in water prior to use and it would be obvious for deposit of the active agent on the tooth surface.

Therefore one of ordinary skill in the art would have known to combine the teachings of the above cited reference to make and used the claimed invention at the time it was made because the invention is known to the ordinary skill in the art.

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

One of ordinary skill in the art would have combined the teachings of Lawlor with that of Aberg to make an oral dentrifice tablet that is non-effervescent, pH in the range 7.5-12 of chewable, leave a substantial amount of the composition on the tooth surface because the active agent for a composition of a tooth tablet are well known within the art. One of ordinary skill in the art would know how to prepare a composition of this nature as the techniques are well known to the one of ordinary skill in the art.

One of ordinary skill in the art would have been motivated to combine the teachings of the above cited prior art and expect a successful result in doing so, because the aim of preventive dentistry has been to improve the efficacy of oral hygiene and overall health in mammals.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
10/20/05

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER